DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

#16

Re: AMARYL®
Docket No. 96E-0044

MAY 14 1996

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,379,785, filed by Hoechst Atiengesellschaft, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for AMARYL®, the human drug product claimed by the patent.

The total length of the regulatory review period for AMARYL® is 2,683 days. Of this time, 2,225 days occurred during the testing phase and 458 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: July 28, 1988.

   FDA has verified the applicant's claim that the date the Investigational New Drug application became effective was on July 28, 1988.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: August 30, 1994.

   FDA has verified the applicant's claim that the New Drug Application (NDA) for AMARYL® (NDA 20-496) was initially submitted on August 30, 1994.

3. The date the application was approved: November 30, 1995.

   FDA has verified the applicant's claim that NDA 20-496 was approved on November 30, 1995.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Barbara V. Maurer, Esq.
Hoechst Celanese Corporation
Route #202-206, Patent Department
P.O. Box 2500
Somerville, NJ 08876-1258